REMARKS

The Office Action dated June 18, 2003 has been carefully reviewed. Reconsideration of this application is respectfully requested.

US-5641323 (Caldarise)

The Examiner has rejected unspecified claims under §102(b) based on US-5641323 (Caldarise). The rejection is respectfully traversed.

Caldarise was involved in the mid-1990's in developments in the use of deposition techniques (termed "3-D printing techniques") in the manufacture of orthopaedic prostheses. In these techniques, articles are made from powders by depositing a first densely packed powder material in a confined region, and applying a binder to selected regions of the first powder material to solidify it in a pre-determined pattern. This work is the subject of US-5641323 which the Examiner has cited in the search report. It is also the subject of US-5788916 which the Examiner has considered (see PTO-1449 attached to the office action).

In the '323 document, the printing technique is applied using ceramic forming materials such as alumina, silica, silicon carbide and so on. In the '916 document, this work is taken further. This document includes a detailed discussion of the use of the 3-D printing or casting technique to form a component of a joint prosthesis which is ceramic. For example, at lines 13 to 29 of column 4 of US-5788916, there is a discussion of acetabular shell components which are constructed from metallic and ceramic parts. An internal portion of the

acetabular shell is formed from a ceramic material that is concave and cup-like in shape (see Figures 2 and 2A). The manufacture of the acetabular shell is discussed in column 6 beginning at line 9, with specific reference to the 3-D printing techniques which are described above.

The 3-D printing techniques which are promoted by Caldarise for forming the ceramic articles are disclosed in US-5204055 (Sachs). The subject matter disclosed in the Sachs document is specifically incorporated in the specifications of each of the Caldarise patents by reference. It is readily apparent to the skilled reader that ceramic materials which are produced using the Sachs technique are low density materials. This is an inevitable result of the use of, initially, a powder distribution head and, subsequently, a binder deposition head. The binder deposition head is specifically referred to in the Sachs document as "an ink-jet print head" (see column 4 lines 1 to 7). At column 4 line 45, it is stated that the powder particles can be packed at high densities; however, the packing density is limited by the use of a deposition technique for laying down the particles.

It is a direct consequence of the use of the deposition techniques described in the Sachs document for the powder and binder components that the density of the resulting ceramic materials will be low. A direct consequence of the low density of the materials is that their hardness will also be low, and they will have a low wear resistance. Techniques exist for forming high density ceramic components which are hard, but these are not in any way contemplated in the Sachs document or in the Caldarise documents, and they would not be consistent with the use of successive deposition steps as in the Sachs technique.

The claimed invention

The invention provides an orthopaedic joint prosthesis in which the contacting bearing surfaces are provided by metallic and ceramic materials respectively. The hardness of the metallic material is required to be at least about 2500 megapascals (MPa) and the hardness of the ceramic material is required to be greater than that of the metallic material by at least about 4000 MPa. It follows directly from the definition of the invention in claim 1 that the hardness of the ceramic material in the claimed prosthesis cannot be less 6500 MPa.

35 USC §102(b) rejection

To the extent that the Caldarise documents provide any indication of ceramic material hardnesses, this is restricted to what can be inferred from the Sachs document. The use of the low impact ink-jet deposition techniques discussed therein is inconsistent with the creation of high density hard materials - the disclosed techniques could not produce such materials.

The present invention involves the specific use of ceramic materials which have a particular hardness characteristics. These characteristics are not disclosed in either of the Caldarise documents, considered either alone or in combination with the Sachs document, which are concerned with the use of materials which will have clearly different characteristics. In the absence of any disclosure of the specified hardness characteristics, the prosthesis defined in

claim 1 is novel. It is therefore submitted that claim 1 complies with the requirements of §102(b) and the Examiner is requested to reconsider the rejection of the claim.

35 USC §103

The Caldarise documents include references to metal-metal, ceramic-ceramic and metal-ceramic articulation couples. The documents include discussion of provision of ceramic components using the deposition techniques which are the subject of the Sachs document. The '323 document suggests that the tendency to form wear debris due to articulation of a joint can be eliminated by provision of passageways through which synovial fluid can flow to the articulation interface. This self-lubrication effect is said to reduce the tendency of joints to form wear debris. The synovial fluid is said to provide sufficient lubricity to enable metal/metal articulation couples to be used effectively in an artificial joint without a [polyethylene] liner material (column 4 lines 18 to 26).

The present invention takes a different approach. It involves the selection of materials for the articulating surfaces of the joint with specified hardness characteristics. The characteristics which are selected for the present invention are not in any way suggested by the Caldarise documents - the only discussion of ceramic materials in the Caldarise documents, in particular when read with the teachings of the incorporated Sachs document, relates to materials which, by virtue of the process by which they are made, are inevitably low density and prone to wear. According to the present invention, a prosthesis makes use

of a ceramic material for one of the bearing surfaces whose hardness is at least 6500 MPa, and is greater than that of the metal of the other bearing surface by at least 2500 MPa. Such properties can be obtained by exposing the ceramic material during its manufacture to high temperature and pressure. The exposure to high pressure results in the material having low porosity and, as a consequence, high density and good resistance to wear. There is no teaching in the Caldarise documents to take this approach. The skilled reader can derive no suggestion whatsoever from these documents to make a prosthesis having these features.

Significant advantages arise from the combination of materials which are used in the prosthesis of the invention. Components with bearing surfaces formed from metallic and ceramic materials can be formed with very smooth surfaces and with accurately controlled geometry so that the surfaces can be accurately matched. The materials used in the prosthesis of the invention can be selected with very high hardnesses. The maintenance of the difference between the hardnesses of the component surfaces means that one of the surfaces will remain smooth during articulation possibility of forming the surfaces so that any wear of the articulating surfaces to ensure close conformance will be restricted to just one of the surfaces. This principle has been adopted in conventional joint prostheses: in the metal on polymer prostheses which are acknowledged in the introduction to the Caldarise patents, conformance can be established by wear of the polymer component. The present invention provides a prosthesis system in which conformance can be achieved as a result of differential hardness while the

geometry one of the surfaces (the ceramic surface) remains unaffected. This can be achieved specifically by selecting materials with the hardness characteristics specified in claim 1. These features are not in any way apparent to the skilled reader of the Caldarise documents. The documents mention metal-metal and ceramic-ceramic couples as well as making passing references to metal-ceramic couples. Some ceramic materials are discussed: as a result of the use of the deposition manufacture technique, these cannot have the hardness characteristics specified in claim 1. The teachings of the Caldarise documents cannot therefore provide the advantages of the present invention.

It is therefore submitted that the Caldarise documents do not make the present invention obvious. Claim 1 is therefore considered to comply with the requirements of §103 in view of what is disclosed in the documents.

Each of claims 2 to 11 is dependent on claim 1 and is therefore also considered to comply with the requirements of §103, for the reasons set out above in relation to claim 1 and for other reasons.

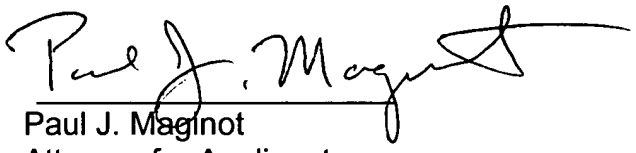
Neither of the Davidson and Farrar documents (US-5037438 and EP-841041) discloses a prosthesis in which the bearing surfaces are provided by metal and ceramic with the characteristics specified in claim 1. These documents are considered not to affect the patentability of the prosthesis of claim 1 adversely.

Conclusion

In view of the foregoing remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

Respectfully submitted,

MAGINOT, MOORE & BECK LLP



Paul J. Maginot
Attorney for Applicant
Registration No. 34,984

November 18, 2003

Maginot, Moore & Beck
Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204-5115
Phone: (317) 638-2922
Fax: (317) 638-2139